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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------------------|------------------------|
| 09/429,331 | 10/28/1999 | LISA A. PAIGE | PAIGE=1D | 5796 |
| 1444 7590 08/24/2007 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303 | | | EXAMINER WESSENDORF, TERESA D | |
| | | | ART UNIT 1639 | PAPER NUMBER |
| | | | MAIL DATE 08/24/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/429,331

Applicant(s)

PAIGE ET AL.

Examiner

T. D. Wessendorf

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 135-139, 142-146, 148-153 and 155-157 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 135-139, 142-146, 148-153 and 155-157 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

ETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/1/07 has been entered.

Status of Claims

Claims 135-139, 142-146, 148-153 and 155-157 are pending and under examination.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 135-139, 142-146, 148-153 and 155-157 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claimed method of predicting the receptor modulating activity of a test compound does not fall into the above

Art Unit: 1639

statutory subject matter requirement of process of making or using. It is not clear as to the utility of a method which predicts that a compound would have the claimed function using the process steps. It seems that the process of predicting the function of a compound has not been fully developed such that a compound is positively identified to have the asserted function. The lengthy specification provides only prophetic statements and not a positive description of the claimed method. The court in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966) held that:

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and **until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. . . . a patent is not a hunting license. . . . [i]t is not a reward for the search, but compensation for its successful conclusion.**

Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner*, 148 USPQ at 696. (Emphasis added).

Thus, at the time of applicants' invention the claimed method of predicting whether a compound has the claimed function does not have a patentable utility. It presents simply a wish to know the identity of any material with that biological property. If applicants were merely wishing

Art Unit: 1639

to predict were whether a compound would possess an effect or activity, then it appears that the method is still incomplete and has not successfully reached a conclusion. It is little wonder that the specification provides only proposals or prophetic statements as to how the method can be accomplished.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 135-139, 142-146, 148-153 and 155-157, as amended, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed method of predicting a compound that modulates a receptor when bound to it is not described in the specification. The disclosure is full of general and prophetic statements as to the numerous and different embodiments of the invention. It is incomprehensible from the numerous embodiments

Art Unit: 1639

as to what actually are being made or described specifically as it pertains to the present claimed method.

Claim Rejections - 35 USC § 112, second paragraph

Claims 135-139, 142-146, 148-153 and 155-157 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention and reiterated below only for paragraph A.

A). Claim 136 is unclear as to what constitutes a panel-based descriptor, especially in the absence of positive definition or recitation in the specification.

Response to Arguments

Applicants submit that only when a claim term is "insolubly ambiguous" (i.e., completely incapable of understanding) should it be deemed indefinite. Applicants further submit that claim 136 has been cancelled.

In reply, the claims are indeed so insolubly ambiguous that it precludes a reasonable search of the prior art. Furthermore, claim 136 has not been cancelled hence, this rejection is maintained. (Applicants are requested to check for other claims that contain said phrase).

B). Claim 135 is insolubly ambiguous (see applicants definition above) since it is not clear as to what is included

Art Unit: 1639

or precluded in the claimed method. For example, it is unclear as to the reference conformation formation between an estrogen receptor and the reference compound. It is also unclear as to the formation of a reference conformation and the reaction of said conformation to a panel of the different ER. (It is suggested that applicants recite the full name of the abbreviated terms). The claim is also indefinite as the claimed steps lack nexus with one other. Since claim 35, the independent claim is insolubly ambiguous hence the claims that depend on it are also insolubly ambiguous. For example, claim 137 is unclear as to step a) which recites providing a ligand to the receptor. Is the ligand different from the reference compound? The specification does not aid in the clarity of the claims. The specification with its 274 pages present terms that are not art-recognized and provides only prophetic statements.

Double Patenting

Claims 135-139, 142-146, 148-153 and 155-157 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2 and 6 of U.S. Patent No. 6,617,114 ('114 Patent) for reasons set forth in the last Office action.

Response to Arguments

Applicants submit that the instant claims recite that the receptor-mediated activity of a test compound bound to a receptor can be predicted by using a panel to obtain a fingerprint corresponding to how the test compound interacts with the receptor in its various panel-modified conformations. The similarity of the fingerprint of the test compound to the fingerprint of a reference compound of known biological activity can then be calculated and used to predict the biological activity of the test compound. Further, applicants submit that the panel members act as probes to survey conformational changes in the receptor. This feature, namely, predicting the receptor-modulating activity of a test compound when bound to a receptor, is believed to patentably distinguish the current claims.

In reply, applicants' arguments are unclear as to predicting the biological activity of the test compound when this is compare to a reference compound of known biological activity. Comparison with a known compound activity to a reference compound identifies (not predicts) said test compound. Furthermore, the reference to the conformational changes in the receptor by the panel members is unclear as to how it corresponds to the modulating activity of the test compound. Thus, the terms "identifying" and "predicting" appear merely a

Art Unit: 1639

difference in semantics. The claims are not read in vacuum but read in the light of the specification. So read, the specification at page 18, lines 9-17 states:

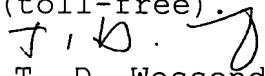
This method provides a simple and consistent means for **identifying** and characterizing modulators of receptor activity, using 'BioKey' oligomers (especially peptides) to probe receptor conformation. It can be used as a tool in both primary and secondary screens for compounds that modulate the activity of a receptor.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw

August 9, 2007